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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,146

05/05/2006

Shyam S. Mohapatra

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SALIWANCHIK LLOYD & SALIWANCHIK

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

11/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/544,146	Applicant(s) MOHAPATRA ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 7, 8, 10, 11, 16, 17, 22-30, 34, 36, 37, 42, 45, 46 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) 1, 7, 8, 10, 11, 16, 17, 22-30, 34, 36, 37 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43, 45, and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/9/07</u> 8-28-06 | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

An amendment was filed on 11/1/07. Claims 2-6, 9, 12-15, 18-21, 31-33, 35, 38-41, 43, 44, and 47 were canceled, and claim 50 was added as requested.

Claims 1, 7, 8, 10, 11, 16, 17, 22-30, 34, 36, 37, 42, 45, 46, and 48-50 are pending.

Applicant's election of group 4 in the reply filed on 11/1/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 7, 8, 10, 11, 16, 17, 22-30, 34, 36, 37, and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/1/07.

Claims 43, 45, and 46 are under consideration.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43,45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adelman et al (Insect Mol. Biol. 10(3): 265-273, 2001) in view of Adelman et al (J. Virol. 76(24): 12925-12933, 2002).

The invention is a method for inhibiting the expression of Dengue virus genes within a host comprising administering to the host an expression vector comprising a polynucleotide encoding an siRNA that reduces expression of a target Dengue virus gene by RNA interference.

Adelman (2001) taught a method of inhibiting the expression of Dengue virus transcripts in mosquito hosts by RNA interference, comprising delivering to the mosquitoes Sindbis expression vectors encoding either sense or antisense RNA directed against regions of the Dengue virus type 2 genome. See abstract; second full paragraph of column 2 on page 266; and first full paragraph of column 1 on page 270.

Adelman (2001) did not teach a vector encoding an siRNA.

Adelman (2002) taught a plasmid vector encoding an siRNA directed against Dengue virus. The plasmid was designed to transcribe an inverted repeat RNA derived from the genome of Dengue virus. See abstract. Adelman (2002) reiterated the finding from Adelman (2001), i.e. stated that expression from a Sindbis vector of RNA with antisense polarity and that of RNA with sense polarity were equally effective to induce resistance to DEN-2 in mosquito cells and adult mosquitoes, noting that virus resistance had many of the characteristics of RNA silencing, including the presence of Dengue virus-specific siRNA. In the 2002 paper Adelman showed that expression of a nuclear transcript that is capable of forming dsRNA provides a more efficient trigger of

viral interference than does expression of transcripts with either sense or antisense polarity, giving further evidence that the presence of intracellular dsRNA triggers RNA silencing in mosquito cells. See page 12931, column 2, first full paragraph.

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Adelman (2001) by delivering to a mosquito host an expression vector designed to transcribe an inverted repeat RNA derived from the genome of Dengue virus, as taught by Adelman (2002). One would have been motivated to do so because Adelman (2002) indicated that such vectors provided a more efficient trigger of RNA interference in mosquito cells than did vectors expressing only sense or antisense RNA. Note that the instant specification at page 11, lines 6-12 defines siRNAs to include hairpin structures, and so the definition is not limited to e.g. 21-23 base pair dsRNA products of Dicer, and so the claim term "siRNA" would include the hairpin RNAs of Adelman (2002). In any event expression of the RNAs led to accumulation of siRNAs of 21-25 nucleotides in length (see page 12930, column 2).

It is noted that the combined references teach administration of interfering RNAs prior to challenge with Dengue virus, and not to mosquitoes already infected with Dengue virus. It would have been similarly obvious to administer the siRNA vector to mosquitoes that had been previously infected because one of ordinary skill could reasonably expect to achieve similar inhibition of virus expression. MPEP 2144.04 states that the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results citing *Ex parte Rubin*, 128 USPQ 440 (Bd.

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App. 1959), In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), and In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930).

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.  
Primary Examiner  
Art Unit 1635